

PATENT APPLICATION

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE



In re the Application of Timothy P. Croughan

Examiner Kruse, David H.

Serial No. 09/934,973

Group 1638

Filed August 22, 2001

For: Herbicide Resistant Rice

Atty. File 98A9-USC1 Croughan

REQUEST FOR CONTINUED EXAMINATION UNDER 37 C.F.R. § 1.114

Mail Stop RCE
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

This Request for Continued Examination is submitted in response to the Final Action dated July 25, 2003.

Remarks

No further amendments are presented.

Claims 62-73 and 75-81 remain in the application.

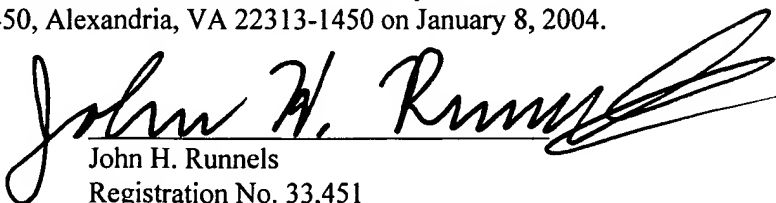
CERTIFICATE

I hereby certify that this Request for Continued Examination, and the accompanying check for \$1720 are being deposited with the United States Postal Service as first class mail in an envelope addressed to: Mail Stop RCE, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on January 8, 2004.

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John H. Runnels
Registration No. 33,451
January 8, 2004

Claims 63, 65, 67, 69, 71-73, 76, 78, and 80 have been held to be withdrawn from consideration.

Enclosed is a check for \$1720 to cover both the fee for a Request for Continued Examination, and the fee for a three-month extension of time, to extend the time for response from October 25, 2003 to January 25, 2004. (37 C.F.R. § 1.136(a)(3)). If this amount is incorrect, please refer to the Deposit Account Authorization previously filed for this application. If any additional extension of time is required, please consider this paper a petition for the total extension of time required.

Reexamination and reconsideration of the application, as amended, are respectfully requested.

Topic numbers in the headings below (e.g., "6 and 9" in the heading immediately below) correspond to those appearing in the August 13, 2003 Office Action. Topic numbers omitted below (e.g., 1-5) are believed not to require any response from the Applicant.

**6 and 9. The Non-Elected Process Claims Should be Rejoined
After the Product Claims Have Been Allowed**

Please note that the non-elected Claims are still pending in this application, and have not been cancelled.

Applicant respectfully submits that once the elected Claims to the rice plants have been allowed, the non-elected Claims directed to processes for making and using the rice plants should then be rejoined and examined in the same application. In particular, the Office's attention is respectfully directed to M.P.E.P. § 821.04, which provides for rejoinder of process Claims in such a case.

Note particularly that rejoinder under M.P.E.P. § 821.04 does not depend upon whether the original election was made with or without traverse.

Applicant interprets the Office's July 25, 2003 comments on this point as being in agreement with Applicant's position in principle.

10. The Written Description Rejection

Claims 62, 64, 66, 68, 70, 75, 77, 79, and 81 were rejected as containing subject matter that lacked an adequate written description in the specification.

Although the February 11, 2003 Office Action cited M.P.E.P. § 2163 in support of this ground of rejection, the Office Action apparently overlooked the “strong presumption” recognized by M.P.E.P. § 2163, subpart (I)(A), first paragraph: “There is a strong presumption that an adequate written description of the claimed invention is present when the application is filed.” (citation omitted)

The preliminary amendment that was filed on August 22, 2001 in no way alters this “strong presumption,” because nothing in the Office’s written description rejection dealt with any limitation that was altered by the Preliminary Amendment. Furthermore, as was discussed in greater detail in the Preliminary Amendment, those amendments primarily concerned either clarifications that were not intended to change the scope of the claims; or concerned incorporating the substance of Claim 74 as originally filed into independent Claim 71. There was, however, one part of the amendment to Claim 71 that did change its scope. Likewise, the May 13, 2003 amendments concerned formal matters only, and were not intended to change the scope of the Claims in any manner.

Thus, with the arguable exception of the one part of the Preliminary Amendment that altered the scope of Claim 71, all Claims continue to be entitled to the “strong presumption” of M.P.E.P. § 2163 that an adequate written description is present. With all respect, the Office has not rebutted this strong presumption.

As stated in M.P.E.P. § 2163, subpart (II)(A)(3)(a), first paragraph: “Possession may be shown in many ways. For example, possession may be shown by describing an actual reduction to practice of the claimed invention.” See also M.P.E.P. § 2163, subpart (II)(A)(3)(a)(ii), first paragraph: “The written description requirement for a claimed genus may be satisfied through sufficient description of a representative number of species by actual reduction to practice”

A sufficient written description for a claimed genus exists where, as is the case here, the specification gives a sufficient description of the reduction to practice of a representative

number of species. The present specification describes not just paper examples, not just a single example, not just a couple of examples. Rather, the specification describes, in detail, the actual reduction to practice of twenty-seven species of herbicide resistant rice in accordance with the present invention. See, e.g., page 8, line 1 through page 11, line 31. All but five of these twenty-seven species were deposited with ATCC. See, e.g., page 9, line 25 through page 10, line 10; and page 11, lines 7-21. (Note that the apparent "volunteers," herbicide resistant lines that appeared to be identical to the earlier ATCC 97523 line, possibly from seeds lying dormant in the soil between seasons, were not counted as being among these twenty-seven species. Page 24, lines 1-4.)

The actual reduction to practice of twenty-seven species, with ATCC deposits of twenty-two of those species, is more than ample to support generic claims.

The preceding discussion should alone suffice to demonstrate that the present application satisfies the written description requirement. But for the sake of completeness, and in the event that prosecution of this application might thereby be accelerated, below are brief answers to three questions raised on pages 3 and 4 of the July 25, 2003 Office Action.

(1) The Office Action asserted that the Applicant had not described the specific mutations. The mutations are those that result in: a rice plant (1) that "is resistant to inhibition by at least one herbicide that normally inhibits acetohydroxyacid synthase, at levels of the herbicide that would normally inhibit the growth of a rice plant" and (2) that expresses "a functional acetohydroxyacid synthase that is resistant to inhibition by at least one herbicide that normally inhibits acetohydroxyacid synthase, at levels of the herbicide that would normally inhibit the growth of a rice plant." Thus whether a particular rice plant satisfies these limitations might, for example, be identified by a straightforward, two-part test: (1) determine whether the rice plant exhibits resistance to such a herbicide, under conditions that inhibit a control rice plant lacking herbicide resistance; and (2) determine whether the rice plant expresses an AHAS enzyme that is resistant at the enzyme level to normally inhibitory levels of herbicide. Examples of both types of tests are given in the specification. For example, the plant-level test is exemplified by the experiments described on pages 12-23; and the enzyme-level test is exemplified by the assays described on page 7, lines 13-30.

(ii) The Office rejected Applicant's assertion that no prior source of AHAS herbicide resistance was known in rice, based on Terakawa. Terakawa is discussed below in connection with the prior art rejections.

(iii) The Office Action noted that Applicant does not know the mechanism of herbicide resistance in the ATCC 75295 line, other than that it does not involve a resistant AHAS enzyme. A limitation concerning ATCC 75295 appears only in dependent Claim 81, where an "ATCC 75295 derivative" limitation is added to the limitations of independent Claim 75. The patent law imposes no requirement that an inventor must understand why an invention works. It suffices that the invention does in fact work. To the present day, the mechanism of herbicide resistance in ATCC 75295 is not understood. However, as the Office has previously recognized -- for example, in issuing patent 5,545,822, which contains claims directed to rice line ATCC 75295 and its derivatives and progeny -- an inventor need not be able to explain why an invention works in order for the invention to be patentable. Note further that, unlike some of the broader limitations appearing in other Claims, the "ATCC 75295" limitation of Claim 81 is not directed to a generic description of a category of herbicide resistance; rather, that limitation requires specifically that "said plant is a derivative of the plant with ATCC accession number 75295, and said plant additionally has the herbicide resistance characteristics of the plant with ATCC accession number 75295." Thus this limitation does not go beyond the written description.

Written description summary

It is respectfully submitted that the written description rejection should be withdrawn.

13. The Enablement Rejection

Claims 62, 64, 66, 68, 70, 75, 77, 79, and 81 were rejected as containing subject matter that was not enabled by the specification.

The May 13, 2003 Amendment gave a detailed rebuttal of the reasons previously given by the Office in support of the enablement rejection. Except for certain remarks concerning ATCC 75295, the July 13, 2003 Office Action did not directly respond to Applicant's arguments. Instead, the Office Action merely stated that "they are not

persuasive,” and made some remarks about whether the claimed sources of herbicide resistance could be distinguished from other sources of herbicide resistance.

In the interest of brevity, Applicant will not repeat the May 13, 2003 remarks, which are again re-urged. If the Office disagrees with any of those remarks, the Office is respectfully requested to give detailed reasons for its disagreement, so that a more responsive reply might be made.

Regarding ATCC 75295, Applicant repeats the May 13, 2003 remarks, and further notes that this question affects only dependent claim 81, not any of the other claims.

Applicant offers the following observation on the Office’s assertion that other sources of herbicide resistance were known. (July 25, 2003 Office Action, page 5, first full paragraph). With all respect, the Office has not documented this assertion, aside from references offered by the Office in support of the § 102 / § 103 rejections. For the reasons given below, it is respectfully submitted that the prior art rejections should be withdrawn. Furthermore, the Office is respectfully requested to explain why the possible existence of other sources of herbicide resistance in rice, outside the scope of the claimed invention, would have a bearing on the question of enablement anyway. The Office’s contention is unclear. The Office is respectfully requested to clarify this contention, or to withdraw it.

The Office has also suggested that, in light of the negative limitation of Claim 62, undue experimentation would be required to determine whether the “ATCC 97523” exclusion applies. With all respect, the Office is mistaken. In issuing the 5,952,553 patent (which is of record in this case), the Office has already determined that the invention defined, for example, in Claim 1 of the ’553 patent may be practiced without undue experimentation, and that the scope of that claim is clear. Since the limitations of parts (b) and (c) of claim 1 of the ’553 patent closely track the limitations of claim 62 of the present application, the Office’s position on this point contradicts the position taken by the Office in issuing the ’553 patent. The Office was correct in issuing the ’553 patent, and should withdraw this ground of rejection.

Enablement Summary

It is respectfully submitted that all grounds of rejection pertaining to enablement should be withdrawn.

12 and 13. The § 102(b) and § 103 Rejections

Claims 62, 64, 66, 68, 70, 75, 77, and 79 were rejected under 35 U.S.C. § 102(b) or § 103 as being anticipated by or obvious over Terakawa, in some cases in combination with Croughan 1994.

For the reasons given in the May 13, 2003 Amendment – reasons that will not be repeated in the interest of brevity – it is respectfully submitted that the prior art rejections should be withdrawn. For the reasons given in the prior Amendment, it is respectfully submitted that the Terakawa paper on its face is clearly distinguishable from the claimed inventions. Applicant continues to urge this position, and the discussion appearing below should not be construed to the contrary.

In the interest of accelerating prosecution, the Applicant is currently seeking to obtain samples of the seed mentioned in the Terakawa paper from the authors of that paper. (a) If the seed is available, then herbicide tolerance tests will be conducted to compare directly the herbicide tolerance profiles of the Terakawa rice lines and of the claimed inventions. (b) Alternatively, it might be the case that this seed is no longer available. If the seed were no longer available, then Terakawa would not be an enabling disclosure with respect to the specific rice lines in question. A nonenabling disclosure cannot anticipate a claimed invention; nor could a nonenabling disclosure make a claimed invention obvious.

For the reasons given in the May 13, 2003 Amendment, it is respectfully submitted that the prior art rejections should be withdrawn. Alternatively, the results of the Terakawa *et al.* inquiry and, if applicable, comparative tests will be submitted to the Office when available.

14. The Obviousness-Type Double Patenting Rejection

Claims 62, 64, 66, 68, 70, 75, 77, 79, and 81 were rejected for obviousness-type double patenting over Claims 1-9 of Croughan, U.S. Patent 5,773,704.

It is respectfully submitted that there are at least three different reasons why this ground of rejection should be withdrawn: (a) The Office has applied an incorrect legal standard to the double patenting question. (b) Even if the standard applied by the Office Action were legally correct (which it is not), that standard would nevertheless have been applied incorrectly to the facts of this case. (c) Under the correct legal standard, applied correctly to the facts of this case, there is no obviousness-type double patenting.

The same arguments were submitted in the May 13, 2003 Amendment, but the Office did not respond other than in a conclusory fashion to say that "they are not persuasive." Should the Office repeat this provisional rejection, the Office is respectfully requested to respond directly to Applicant's arguments, so that a responsive reply might be formulated. It is difficult for the Applicant to prepare a meaningful reply on this point, where the Applicant has previously given a specific traversal of the provisional rejection, and the Office has offered no substantial response. The Office's attention is respectfully directed to M.P.E.P. § 707.07(f).

For the reasons given below, it is respectfully submitted that this provisional ground of rejection should be withdrawn. But if the Office should instead repeat the provisional ground of rejection, then the Office is specifically requested to:

- (a) Clearly articulate the legal standard that the Office has applied, and to cite governing authority in support of that legal standard;
- (b) Respond to Applicant's specific arguments below that the Office's conclusions were based on incorrect factual assumptions; and

(c) Respond to Applicant's specific arguments below that when the correct legal standard is applied to the actual facts, there is no obviousness-type double patenting.

(a) The standard applied by the Office concerning double patenting is legally incorrect. Without citing any supporting authority, the standard applied by the Office Action appears to be whether a person of ordinary skill in the art would be able to distinguish a derivative plant covered by the Claims of the '704 patent from a derivative plant covered by the claims of the present application.

This is not the correct legal standard for evaluating obviousness-type double patenting. The correct standard is instead the following: "does any claim in the application define an invention that is merely an obvious variation of an invention claimed in the patent?" M.P.E.P. § 804, subpart (II)(B)(1), first paragraph. Under the correct legal standard, the proper comparison is between two claims -- not a comparison between two embodiments.

Brief reflection will readily demonstrate that it would be inappropriate for the governing standard to be whether an embodiment covered by an issued patent could be distinguished from an embodiment covered by a claim in a pending application. As the discussion in M.P.E.P. § 804 demonstrates (e.g., subpart (II)(B)(1)(b)), obviousness-type double patenting questions often arise in the context of a broader genus claim versus a narrower species claim presented in different patent(s) or application(s). If the proper standard were merely whether embodiments could be distinguished, then obviousness-type double patenting would always exist between a genus claim and a species claim presented in different patent(s) or application(s), because an embodiment covered by a specific claim would always be covered by the generic claim. A large part of the discussion in the M.P.E.P. concerning double patenting would then be moot. However, comparison of embodiments is not the proper legal standard. Instead, one compares Claims.

(b) Even if the standard applied in the Office Action were legally correct (which it is not), the Office nevertheless would have incorrectly applied that standard to the facts of this

case. Although it is not logically necessary for the Applicant to demonstrate this point in order to overcome the double patenting rejection, it will nevertheless be discussed briefly, in case doing so might help accelerate the prosecution of this application. The Office Action stated at page 9: "Because the issued claims do not limit the number of generations away from the deposited plant, the herbicide-resistant rice plant of the instant claims would be obvious, because one of ordinary skill in the art would not be able to distinguish the 'derivative' plant of the patented herbicide-resistant rice plant from the 'derivative' plant of the instant claims."

As previously discussed, "derivative" plants must retain the specified herbicide resistance characteristics. The herbicide resistance characteristics are themselves typically distinguishable from one another. Different sources of herbicide resistance typically have different patterns of resistance to different levels of different herbicides. See, e.g., the present specification at page 24, lines 1-4, demonstrating that making such a determination is in fact relatively straightforward: "Further examination of these plants led to the conclusion that the following herbicide resistant lines appeared to be identical to prior herbicide resistant line ATCC 97523, presumably because a few seeds of ATCC 97523 from prior trials had remained dormant in the soil between growing seasons: PWC18, PWC20, PWC24, CMC25, CMC26, CMC28, CMC30, WDC32, WDC34, WDC35, and WDC36." (These lines were, accordingly, not among those deposited with ATCC.) Note in particular the last limitation of Claim 62: "wherein these derivatives of the plant with ATCC accession number 97523 that are excluded from the scope of this Claim are those that retain the herbicide resistance characteristics of the plant with ATCC accession number 97523."

In addition to examining patterns of resistance to various herbicides, it should also be kept in mind that, as previously discussed, it is a nearly universal practice in the art that the developer or breeder of a new rice cultivar will disclose publicly the ancestry of the variety (except for a small number of proprietary hybrids). As a practical matter one is very likely to know the pedigree of any publicly released rice cultivar.

For either of these reasons, it will be possible for one of ordinary skill in the art to distinguish derivatives of ATCC 97523 covered by the '704 patent from rice plants covered by the present Claims, which exclude ATCC 97523 and its derivatives.

(c) Under the correct legal standard, applied correctly to the facts of this case, there is no obviousness-type double patenting. The correct legal standard is the following: "does any claim in the application define an invention that is merely an obvious variation of an invention claimed in the patent?" M.P.E.P. § 804, subpart (II)(B)(1), first paragraph.

It is important to keep in mind that when "considering whether the invention defined in the claim of an application is an obvious variation of the invention defined in the claim of a patent, the disclosure of the patent may not be used as prior art." M.P.E.P. § 804, subpart (II)(B)(1), sixth paragraph.

"Any obviousness-type double patenting rejection should make clear: (A) The differences between the inventions defined by the conflicting claims -- a claim in the patent compared to a claim in the application; and (B) The reasons why a person of ordinary skill in the art would conclude that the invention defined in the claim in issue is an obvious variation of the invention defined in a claim in the patent." M.P.E.P. § 804, subpart (II)(B)(1), fifth paragraph.

The Office Action did not even attempt to apply this standard to the double-patenting question. To support this ground of rejection, at a minimum the Office should identify at least one specific Claim from the '704 patent and at least one specific Claim from the present application, and then explain why a person of ordinary skill in the art would conclude that the latter would have been obvious in light of the former. It is respectfully submitted, however, that this is not the case.

For example, Claim 1 of the '704 patent is as follows:

1. A rice plant wherein:

(a) the growth of said plant is resistant to inhibition by one or more of the following herbicides, at levels of herbicide that would normally inhibit the growth of a rice plant: imazethapyr, imazaquin, primisulfuron, nicosulfuron,

sulfometuron, imazapyr, imazameth, imazamox, or a derivative of any of these herbicides;

(b) said plant is a derivative of the plants with ATCC accession numbers 75295 and 97523; and

(c) said plant has the herbicide resistance characteristics of the plants with ATCC accession numbers 75295 and 97523.

By contrast, Claim 62 of the present application reads as follows:

62. (once amended) A herbicide-resistant rice plant, wherein:

(a) the growth of said herbicide-resistant plant is resistant to inhibition by at least one herbicide that normally inhibits acetohydroxyacid synthase, at levels of the herbicide that would normally inhibit the growth of a rice plant; and

(b) said herbicide-resistant plant is a derivative of a rice plant obtained by exposing rice plants to mutation-inducing conditions; growing rice plants from the exposed plants, or growing rice plants from progeny of the exposed plants, in the presence of at least one herbicide that normally inhibits acetohydroxyacid synthase, at levels of the herbicide that would normally inhibit the growth of a rice plant; and selecting for further propagation rice plants that grow without significant injury in the presence of the herbicide; and

(c) said herbicide-resistant plant expresses a functional acetohydroxyacid synthase that is resistant to inhibition by at least one herbicide that normally inhibits acetohydroxyacid synthase, at levels of the herbicide that would normally inhibit the growth of a rice plant;

provided that excluded from the scope of this Claim is:

(d) a plant that is the plant with ATCC accession number 97523; and any mutant, recombinant, or genetically engineered derivative of the plant with ATCC accession number 97523 or of any progeny of the plant with ATCC accession number 97523; and any plant that is the progeny of any of these plants; wherein these derivatives of the plant with ATCC accession number 97523 that are excluded from the scope of this Claim are those that have the same herbicide resistance characteristics as the plant with ATCC accession number 97523.

Note first that Claim 62 expressly excludes derivatives of ATCC 97523. Thus Claim 62 of the present application and Claim 1 of the '704 patent are disjoint -- i.e., there is no overlap between the two Claims.

Note further that, as previously discussed, the ATCC 75295 line mentioned in Claim 1 of the '704 patent does not have a resistant AHAS enzyme.

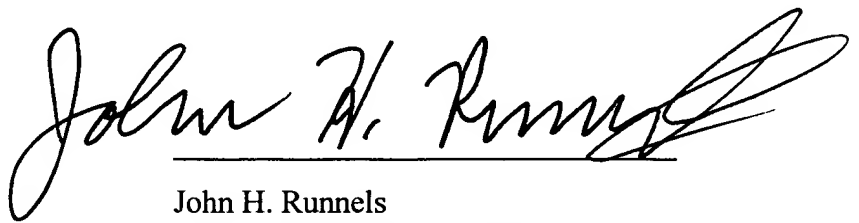
Nothing in Claim 1 of the '704 patent teaches or suggests any herbicide resistant rice plant having a resistant AHAS enzyme, other than the specific source of resistance from ATCC 97523. There is no suggestion for how to make such a plant, and there would have been no reasonable expectation that such a plant could be successfully produced. There would certainly have been no reasonable expectation that resistant rice AHAS enzymes could be produced having herbicide resistance characteristics different from those of the ATCC 97523 rice. With all respect, the July 13, 2003 Office Action does not suggest otherwise.

It is respectfully submitted that the obviousness-type double patenting rejection should be withdrawn.

Conclusion

Allowance of Claims 62-73 and 75-81 at an early date is respectfully requested.

Respectfully submitted,

A handwritten signature in black ink, reading "John H. Runnels". The signature is fluid and cursive, with a horizontal line drawn underneath the name.

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